FOOD DISTRIBUTORS INTERNATIONAL
NAWGA/IFDA

1070

October 28, 2002

BY HAND DELIVERY

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0209; Request for Comment on First Amendment Issues

Dear Sir or Madam:

Food Distributors International (FDI) and the International Foodservice Distributors Association (IFDA) are grateful for this opportunity to submit comments to the Food and Drug Administration (FDA) in response to the agency's Request for Comment on First Amendment Issues. 67 Fed. Reg. 34,942 (May 16, 2002). FDI and IFDA are writing to endorse comments previously submitted by SureBeam Corporation regarding FDA's disclosure requirement for irradiated foods.

FDI is a trade association comprised of food distribution companies that supply and service independent grocers and foodservice operations throughout the United States, Canada and 19 other countries. The association and its foodservice partner, IFDA, have 218 member companies that operate 997 distribution centers with a combined annual sales volume of $178 billion.

The FDA disclosure requirement for irradiated foods cannot survive scrutiny under the growing body of case law on First Amendment protection of commercial speech. It is now well established that, to be found constitutional, government regulation of commercial speech must be based on a substantial government interest, must directly advance the asserted government interest, and must do so without imposing an unnecessary burden. Central Hudson Gas & Electric Corp. v. Public Service Com'n of New York, 447 U.S. 557, 566 (1980). The disclosure requirement for irradiated foods fails all three prongs of the constitutional test.

1. **The irradiation disclosure requirement is not based on a substantial government interest.**

FDA has consistently maintained that irradiated foods are safe to eat. However, FDA mandated that irradiated foods bear a disclosure statement and the radura logo to alert consumers to the following "material facts": organoleptic changes, changes in shelf life, and the fact that irradiated

02N-0209

D
C92

201 Park Washington Court • Falls Church, VA 22046-4521 • P (703) 532-9400 • F (703) 538-4673

food is "processed" but does not appear to be so. Thus, the asserted government interest on which the irradiation disclosure requirement is based is the interest in preventing consumers from being misled as to the nature ("processed" versus "unprocessed"), organoleptic properties, and shelf life of irradiated foods.

FDA's asserted interest in informing consumers that irradiated foods are "processed" is undercut by the fact that FDA does not treat irradiated foods as "processed foods" in other contexts. For example, irradiated fruits and vegetables are treated as "raw agricultural commodities" for purposes of nutrition labeling, and foods irradiated at doses up to 1 kiloGray may be labeled "fresh." FDA's interest in alerting consumers to the "processed" nature of irradiated foods is further undercut by the fact that FDA has not required disclosure of other food production or processing technologies (e.g., blanching, ultrasound, fumigation, modern biotechnology) that, like irradiation, are not obvious to consumers. FDA has not, and we believe cannot, offer a sound rationale for treating these other technologies differently from irradiation.

FDA's asserted interest in informing consumers that irradiated foods may have altered organoleptic properties or shelf life also does not rise to the level of a substantial government interest. Most irradiated foods undergo little or no change in organoleptic traits or shelf life. To the extent that some irradiated foods do have changed organoleptic properties or shelf life, these changes are frequently beneficial. For there to be a substantial government interest, the government must be able to point to a real harm that its regulation of speech will alleviate. Edenfield v. Fane, 507 U.S. 761, 770-771 (1993). There is no potential harm to consumers in not being informed that a food product has improved organoleptic qualities or a longer shelf life.

2. The irradiation disclosure requirement does not directly advance the government interest asserted by FDA.

If, as FDA has asserted, the purpose of the irradiation disclosure is to alert consumers to the "processed" nature of irradiated foods and the possibility of organoleptic and shelf life changes, the disclosure now mandated does not advance that purpose. We are aware of no evidence that consumers interpret the irradiation disclosure in this way. Rather, consumers tend to view the irradiation disclosure as a warning that irradiated food may be unsafe. As FDA is aware, certain consumer groups have actively spread this misperception.

3. The irradiation disclosure requirement imposes an unnecessary burden on the regulated industry.

Since most irradiated foods undergo little or no change in organoleptic properties or shelf life, a blanket disclosure requirement that applies to all irradiated foods is overly broad and imposes unnecessary burdens. The burden imposed by the irradiation disclosure requirement goes well beyond the labeling costs themselves. As FDA itself has acknowledged, the disclosure requirement

may strengthen negative perceptions of irradiated foods and that industry may need to counter these negative perceptions with "consumer education programs." Despite education programs by both government and industry, these negative perceptions persist and are encouraged by the disclosure requirement itself. The burden imposed on industry by the FDA's blanket irradiation disclosure requirement is both heavy and unnecessary. A disclosure requirement tailored to irradiated foods that do, in fact, have significantly changed organoleptic properties would be defensible.

4. FDA should rescind its regulations mandating disclosure of irradiated foods.

FDA's disclosure requirements for irradiated foods have long been questioned as resting on shaky legal and scientific ground. In light of recent First Amendment precedents, these concerns can no longer be ignored. We urge FDA to rescind the existing disclosure requirement for irradiated foods and issue in its place a guidance document setting forth a new policy on mandatory and voluntary disclosure. FDA should mandate disclosure only where irradiation treatment results in a true material fact (i.e., a significant organoleptic change). FDA should require disclosure of the material fact, not the irradiation treatment itself.

Respectfully submitted,

David French

David French
Vice President, Government Relations